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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,959	06/25/2001	Richard Ian Christopherson	DAVI139.001C1	2583

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,959	CHRISTOPHERSON ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 5, 2004 has been entered.

Claim 3 was canceled. Claim 21 was added.

The election of species requirement of Oct. 2, 2002 is withdrawn.

Claims 1, 2 and 7-21 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The declaration of Richard Ian Christopherson filed under 37 C.F.R. 1.132 has been considered.

Claim Rejections Withdrawn:

4. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of claim 3.

5. The rejection of claim 3 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the cancellation of claim 3.

6. All rejections of the claimed inventions as being anticipated by the prior art are withdrawn view of the amendment.

7. All rejections of the claimed inventions as being unpatentable over the prior art are withdrawn. However, see new grounds of rejection.

New Grounds of Rejection:

8. Claims 1, 2 and 7-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the amendment to claim 1 introduces new matter into the specification.

The amendment filed 3/5/2004 introduces the limitation into claim 1 that "at least 5 of the CD antigens are selected from the list consisting of...". Thus the claimed inventions read on methods using an array comprising at least 5 antibodies to CD antigens. Applicants have failed

to point to passages in the specification that provide support for this new limitation. Upon review of the specification there does not appear to be any support, either implicit or explicit, for an array that comprises at least 5 antibodies having specificity for CD antigens selected from a list of CD antigens. Therefore, one of skill in the art would not find that applicant was in possession of the claimed invention at the time of filing.

9. Claims 1, 2, 7, 8, 11, 15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Valet (cited in a previous Office action).

The claimed inventions are drawn to methods for identifying a type of leukemia in a human subject comprising contacting a sample from the subject with an array comprising immunoglobulin molecules immobilized to a solid support, wherein the immunoglobulin molecules have specificity for CD antigens, wherein at least 5 of the CD antigens are selected from the list presented in claim 1. Therefore, the claimed inventions are interpreted to be drawn to a method comprising the use of an array of immobilized antibodies, where the array comprises at least 5 different antibodies, each having specificity to a different CD antigen.

Chang teaches methods of using antibodies immobilized to a solid support for the purpose of differentiating different cell populations characterized by differential antigen expression, for example the proportion of specific subsets in a mixed population containing B cells, T cells and monocytes (col. 4, line 39-60). Chang teaches that a 100 spot matrix may be used (col. 2, line 54 – col. 3, line 8. Chang also teaches the advantages over tests done with fluorescence flow cytometry. Chang teaches the use of polyclonal and monoclonal antibodies

(col. 3, line 63- col. 4, line 3). The biological sample of Chang encompasses blood and blood cells.

Chang fails to teach the use of an antibody array comprising antibodies that bind to CD antigens for the purpose identifying a type of leukemia.

However, Valet teaches that a series of antibodies specific for CD antigens may be used to distinguish different types of leukemias. The antibodies to CD antigens used in Valet's method are listed on page 277, 1st col. Valet's method uses 12 different antibodies, some of them are antigen binding fragments (as in claim 21). The antibodies of Valet comprise antibodies that are capable of interaction with a CD antigen from CLL (e.g. CD10, CD38, CD19, CD23, CD5); from HCL (e.g. CD11c); from ALL (e.g. CD10, CD38, CD19, CD23, CD5); from AMoL (e.g. CD14).

Therefore, it would have been prima facie obvious at the time the invention was made to have used the diagnostic method of Chang for the purpose of identifying a type of leukemia based on differential CD antigen expression, because Valet teaches a panel of useful antibodies that may be used to distinguish between two different types of leukemia (CLL and IC). One would have been motivated to use the method of Chang in place of the flow cytometric method of Valet because Chang teaches the advantages of using antibodies bound to a solid support as opposed to flow cytometry, where solid support methods allow simultaneous analysis of a large number of antigens compared to the smaller number possible with flow cytometry.

10. Claims 1, 2, and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Terstappen (U.S. Patent 5,234,816; cited in a previous Office action).

Chang teaches methods as described above. Chang fails to teach the use of an antibody array comprising antibodies that bind to CD antigens for the purpose identifying a type of leukemia.

However, Terstappen teaches that a series of antibodies specific for CD antigens may be used to distinguish different types of leukemias. The antibodies of Terstappen comprise antibodies that are capable of interaction with a CD antigen from CLL (e.g. CD10, CD19, CD5); from HCL (e.g. CD11c); from CML (e.g. CD34); from AML (e.g. CD7); from ALL (e.g. CD10, CD19, CD5); from AMML (e.g. CD13); from AEL (e.g. CD13); from AmegL (e.g. CD13); from AMoL (e.g. CD14); from NHL (e.g. CD6); and from APL (e.g. CD13).

Therefore, it would have been prima facie obvious at the time the invention was made to have used the diagnostic method of Chang for the purpose of identifying a type of leukemia based on differential CD antigen expression, because Terstappen teaches methods of using the determination of CD antigen expression for the purposes of identifying types of leukemia. One would have been motivated to use the method of Chang in place of the flow cytometric method of Terstappen because Chang teaches the advantages of using antibodies bound to a solid support as opposed to flow cytometry, where solid support methods allow simultaneous analysis of a large number of antigens compared to the smaller number possible with flow cytometry.

11. Claims 1, 2, 7, 9-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Verwer (U.S. Patent 5,605,805; issued 02/25/1997).

Chang teaches methods as described above. Chang fails to teach the use of an antibody array comprising antibodies that bind to CD antigens for the purpose identifying a type of leukemia.

However, Verwer teaches that a series of antibodies specific for CD antigens may be used to distinguish different types of leukemias such as ALL, AML, AUL, B-CLL. The antibodies of Verwer comprise antibodies that are capable of interaction with a CD antigen from CLL (e.g. CD10, CD19, CD5); from CML (e.g. CD34); from AML (e.g. CD7); from ALL (e.g. CD10, CD19, CD5); from AMML (e.g. CD13); from AEL (e.g. CD13); from AmegL(e.g. CD13); from AMoL (e.g. CD13); and from APL (e.g. CD13).

Therefore, it would have been prima facie obvious at the time the invention was made to have used the diagnostic method of Chang for the purpose of identifying a type of leukemia based on differential CD antigen expression, because Verwer teaches methods of using the determination of CD antigen expression for the purposes of identifying different types of leukemia. One would have been motivated to use the method of Chang in place of the flow cytometric method of Verwere because Chang teaches the advantages of using antibodies bound to a solid support as opposed to flow cytometry, where solid support methods allow simultaneous analysis of a large number of antigens compared to the smaller number possible with flow cytometry.

12. Claims 1, 2, 7, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Orfao de Matos Correira E Vale (U.S. Patent 5,538,855; issued 07/23/1996; cited in the IDS).

Chang teaches methods as described above. Chang fails to teach the use of an antibody array comprising antibodies that bind to CD antigens for the purpose identifying a type of leukemia.

However, Orfao de Matos Correira E Vale teaches that a series of antibodies specific for CD antigens may be used to distinguish different types of subsets of lymphoid populations. Because the different leukemias arise from different subsets of lymphoid populations, the purpose of Orfao de Matos Correira E Vale's methods are the same as that of the claimed methods. The antibodies of Orfao de Matos Correira E Vale comprise antibodies that are capable of interaction with a CD antigen from CLL (e.g. CD19). The antibodies of Orfao de Matos Correira E Vale are those that bind to CD3, CD4, CD8, CD19, CD56 and alternatively the following are also taught to be added: CD14, CD45 and CD16.

Therefore, it would have been prima facie obvious at the time the invention was made to have used the diagnostic method of Chang for the purpose of identifying a type of leukemia based on differential CD antigen expression, because Orfao de Matos Correira E Vale teaches methods of using the determination of CD antigen expression for the purposes of identifying different types of lymphoid populations. One would have been motivated to use the method of Chang in place of the flow cytometric method of Orfao de Matos Correira E Vale because Chang teaches the advantages of using antibodies bound to a solid support as opposed to flow

cytometry, where solid support methods allow simultaneous analysis of a large number of antigens compared to the smaller number possible with flow cytometry.

13. Claims 1, 2, 7-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeffler (U.S.P.G. Pub 2002/0164656; published 11/07/2002; effective filing date 02/04/1998) in view of Terstappen (U.S. Patent 5,234,816; cited in a previous Office action).

Hoeffler teaches methods of using microarrays that comprise antibodies, polyclonal antibodies or antibody fragments for the purpose of cell profiling (see page 7, para 74 – 75; and page 2, para 21). Hoeffler teaches the advantages of microarrays comprising antibodies for the purpose of rapidly screening large numbers of samples. Hoeffler fails to specifically teach the use of arrays comprising antibodies that bind to CD antigens.

However, Terstappen teaches that a series of antibodies specific for CD antigens may be used to distinguish different types of leukemias. The antibodies of Terstappen comprise antibodies that are capable of interaction with a CD antigen from CLL (e.g. CD10, CD19, CD5); from HCL (e.g. CD11c); from CML (e.g. CD34); from AML (e.g. CD7); from ALL (e.g. CD10, CD19, CD5); from AMML (e.g. CD13); from AEL (e.g. CD13); from AmegL(e.g. CD13); from AMoL (e.g. CD14); from NHL (e.g. CD6); and from APL (e.g. CD13).

Therefore, it would have been prima facie obvious at the time the invention was made to have used the diagnostic method of Hoeffler for the purpose of identifying a type of leukemia based on differential CD antigen expression, because Terstappen teaches methods of using the determination of CD antigen expression for the purposes of identifying types of leukemia. One would have been motivated to use the method of Hoeffler in place of the flow cytometric method

of Terstappen because Hoeffler teaches the advantages of using antibodies bound to a solid support as opposed to flow cytometry, where solid support methods allow simultaneous analysis of a large number of antigens compared to the smaller number possible with flow cytometry.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
May 31, 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
6/1/2004